Vaccine Storage and Transport

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2016 Regional Immunization Workshop

MONTANA DPHHS
Healthy People. Healthy Communities.
Department of Public Health & Human Services

Webinar House Keeping

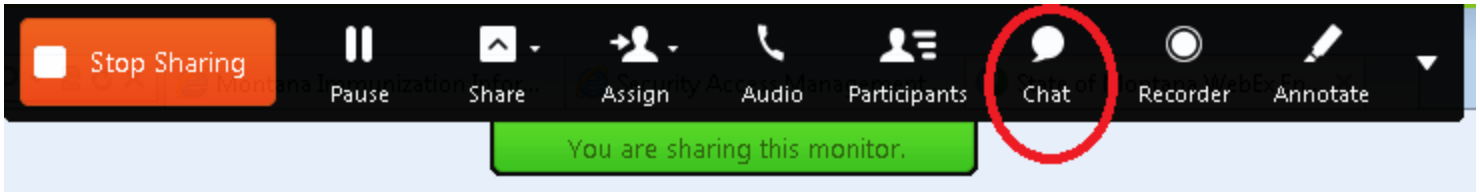
We are muting all participants upon entering the presentation

If you would like to ask a question, please unmute your phone

There is a chat option that allows you to type a question that can be sent to the host or the entire group.

This presentation will be posted to www.immunization.mt.gov under the VFC Training and Resource Page

Let's get started!!

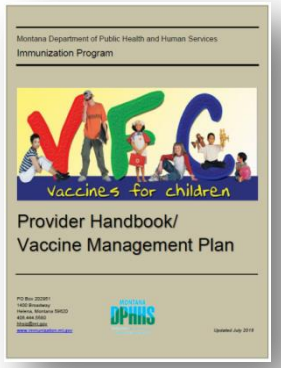


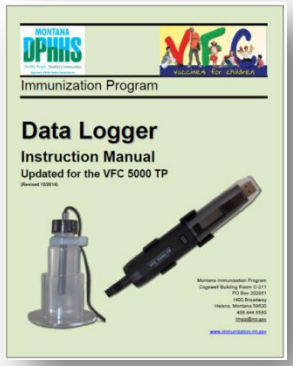
Topics

- Resources for Vaccine Storage
  Prescribing Information/Package Insert
- Vaccine Incident Reports – Behind the Scenes
- Wastage/Negligence – Year in Review
- Data Logger Program Update
- Vaccine Transport
  - New Pack-out for Non-Electric Coolers
  - Electric Coolers

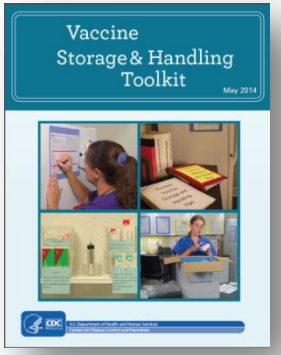
Vaccine Storage Resources

- Montana-Specific:
  - *VFC Provider Handbook*
  - *Data Logger Instruction Manual*





- *CDC Vaccine Storage and Handling Toolkit*



- Professional Prescribing Information (PI)…

Professional Prescribing Information

Aka – "Package Insert"

- Required by law
- Audience – Healthcare Professionals
- Food and Drug Administration (FDA)
  - Develops Rules, Requirements, Format
  - Approves Content
  - Sends electronic updates to EHRs
- Long, complex approval process

Professional Prescribing Information

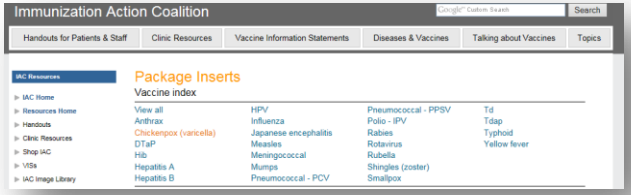
Aka – "Package Insert"

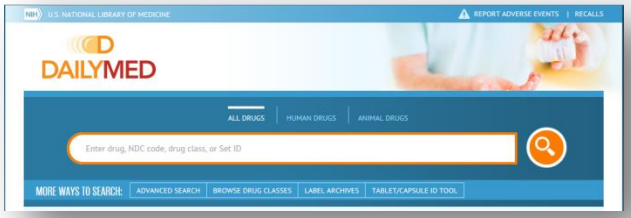
- New format in 2009 aimed at reducing med errors:
  - Standardized sections, added TOC and highlights
  - Improved clarity

- Manufacturers encouraged but not required to switch to the new format. Still variability.

- Found with product and online:
  - Manufacturer website
  - Immunization Action Coalition
  - FDA - http://dailymed.nlm.nih.gov

- Relevance to vaccine storage?
  - Section 16





Professional Prescribing Information

New Format – Page 1

Highlights
(Cliff Notes)

Table of Contents

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VARIVAX safely and effectively. See full prescribing information for VARIVAX.

VARIVAX®
Varicella Virus Vaccine Live
Suspension for subcutaneous injection
Initial U.S. Approval: 1995

----------INDICATIONS AND USAGE----------
VARIVAX is a vaccine indicated for active immunization for the prevention of varicella in individuals 12 months of age and older. (1)

----------DOSAGE AND ADMINISTRATION----------
Each dose is approximately 0.5 mL after reconstitution and is administered by subcutaneous injection. (2.1)
Children (12 months to 12 years of age)
- If a second dose is administered, there should be a minimum interval of 3 months between doses. (2.1)

Adolescents (≥13 years of age) and Adults
- Two doses, to be administered a minimum of 4 weeks apart. (2.1)

----------DOSAGE FORMS AND STRENGTHS----------
Suspension for injection (approximately 0.5-mL dose) supplied as a lyophilized vaccine to be reconstituted using the accompanying sterile diluent. (2.2, 3, 16)

----------CONTRAINDICATIONS----------
- History of severe allergic reaction to any component of the vaccine (including neomycin and gelatin) or to a previous dose of varicella vaccine. (4.1)
- Primary or acquired immunodeficiency states. (4.2)
- Any febrile illness or active infection, including untreated tuberculosis. (4.3)
- Pregnancy. (4.4, 8.1, 17)

----------WARNINGS AND PRECAUTIONS----------
- Evaluate individuals for immune competence prior to administration of VARIVAX if there is a family history of congenital

- Defer vaccination for at least 5 months following blood or plasma transfusions, or administration of immune globulins (IG). (5.5, 7.2)
- Avoid use of salicylates for 6 weeks following administration of VARIVAX to children and adolescents. (5.6, 7.1)

----------ADVERSE REACTIONS----------
- Frequently reported (≥10%) adverse reactions in children ages 1 to 12 years include:
  - fever ≥102.0°F (38.9°C) oral: 14.7%
  - injection-site complaints: 19.3% (6.1)
- Frequently reported (≥10%) adverse reactions in adolescents and adults ages 13 years and older include:
  - fever ≥100.0°F (37.8°C) oral: 10.2%
  - injection-site complaints: 24.4% (6.1)
- Other reported adverse reactions in all age groups include:
  - varicella-like rash (injection site)
  - varicella-like rash (generalized) (6.1)

To report SUSPECTED ADVERSE REACTIONS or exposure during pregnancy or within three months prior to conception, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

----------DRUG INTERACTIONS----------
- Reye syndrome has been reported in children and adolescents following the use of salicylates during wild-type varicella infection. (5.6, 7.1)
- Passively acquired antibodies from blood, plasma, or immunoglobulin potentially may inhibit the response to varicella vaccination. (5.5, 7.2)
- Tuberculin skin testing may be performed before VARIVAX is administered or on the same day, or six weeks following vaccination with VARIVAX. (7.3)

----------USE IN SPECIFIC POPULATIONS----------
Pregnancy: Do not administer VARIVAX to females who are pregnant; the possible effects of the vaccine on fetal development are unknown. Pregnancy should be avoided for 3 months following vaccination with VARIVAX. (4.4, 8.1, 17)

16 HOW SUPPLIED/STORAGE AND HANDLING

17 for PATIENT COUNSELING INFORMATION and -approved patient labeling.

Revised: 07/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

Professional Prescribing Information

New Format – Section 16

Basics:

- How supplied
- Storage temperatures
- Prohibitions

16 HOW SUPPLIED/STORAGE AND HANDLING

PEDIARIX is available in 0.5 mL single-dose disposable prefilled TIP-LOK syringes (packaged without needles):

NDC 58160-811-43 Syringe in Package of 10: NDC 58160-811-52

Store refrigerated between 2° and 8°C (36° and 46°F). Do not freeze. Discard if the vaccine has been frozen.

GARDASIL 9 can be administered provided total (cumulative multiple excursion) time out of refrigeration (at temperatures between 8°C and 25°C) does not exceed 72 hours. Cumulative multiple excursions between 0°C and 2°C are also permitted as long as the total time between 0°C and 2°C does not exceed 72 hours. These are not, however, recommendations for storage.

- Allowed excursions
- Diluent storage conditions
- Latex content info
- Stability after recon

(1) a box of 10 single-dose vials of lyophilized vaccine (package A), NDC 0006-4827-00
(2) a box of 10 vials of diluent (package B).

Storage

Vaccine Vial

During shipment, maintain the vaccine at a temperature between −58°F and +5°F (−50°C and −15°C). Use of dry ice may subject VARIVAX to temperatures colder than −58°F (−50°C).

Before reconstitution, store the lyophilized vaccine in a freezer at a temperature between −58°F and +5°F (−50°C and −15°C). Any freezer (*e.g.*, chest, frost-free) that reliably maintains a temperature between −58°F and +5°F (−50°C and −15°C) and has a separate sealed freezer door is acceptable for storing VARIVAX.VARIVAX may be stored at refrigerator temperature (36°F to 46°F, 2°C to 8°C) for up to 72 continuous hours prior to reconstitution. Vaccine stored at 2°C to 8°C which is not used within 72 hours of removal from +5°F (−15°C) storage should be discarded.

Before reconstitution, protect from light.

DISCARD IF RECONSTITUTED VACCINE IS NOT USED WITHIN 30 MINUTES.

Diluent Vial

The vial of diluent should be stored separately at room temperature (68°F to 77°F, 20°C to 25°C), or in the refrigerator.

For further product information, call 1-800-9-VARIVAX (1-800-982-7482).

Depending on:

- New vaccine
- Updated PI format
- Updated PI information
- Vaccine presentation

Trend towards more permissive storage information in the PI. (e.g., Gardasil)

Professional Prescribing Information

Take Home Message

- Primary resource for product-specific storage information
  But don't get too far in the weeds!

Refrigerated vaccines	35F – 46F
Frozen vaccines	-58F – +5F

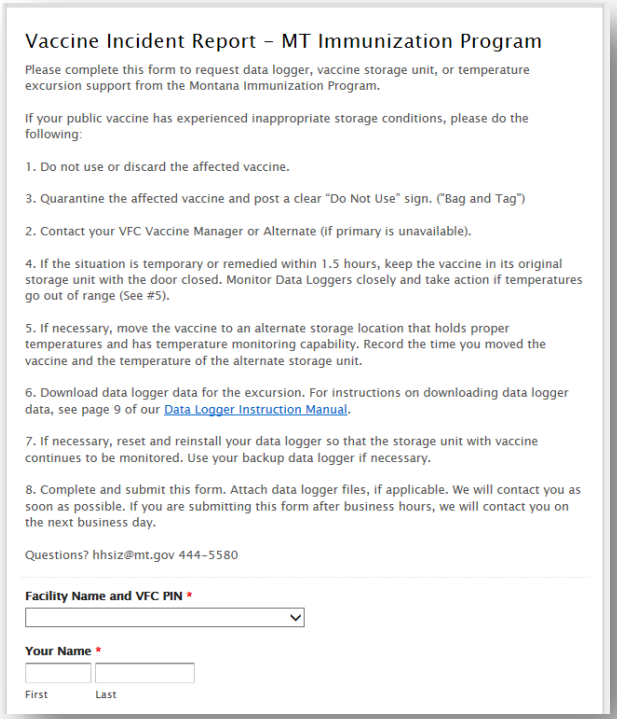
- Find a good resource for up-to-date PI
- First stop for post-excursion information

Vaccine Incident Reports

Behind the Scenes

- VFC providers must notify the Immunization Program of all temperature excursions involving public vaccine.
  - We are required to know about them.
  - We must be involved in viability determinations.
  - Must be documented.

- Online Vaccine Incident Report (VIR)
  - Everyone has used it!
  - Sends notifications to IZ Program Staff
  - Records in a database
  - Replies and resolutions are saved in provider communication file.



Vaccine Incident Report – MT Immunization Program

Please complete this form to request data logger, vaccine storage unit, or temperature excursion support from the Montana Immunization Program.

If your public vaccine has experienced inappropriate storage conditions, please do the following:

1. Do not use or discard the affected vaccine.

3. Quarantine the affected vaccine and post a clear "Do Not Use" sign. ("Bag and Tag")

2. Contact your VFC Vaccine Manager or Alternate (if primary is unavailable).

4. If the situation is temporary or remedied within 1.5 hours, keep the vaccine in its original storage unit with the door closed. Monitor Data Loggers closely and take action if temperatures go out of range (See #5).

5. If necessary, move the vaccine to an alternate storage location that holds proper temperatures and has temperature monitoring capability. Record the time you moved the vaccine and the temperature of the alternate storage unit.

6. Download data logger data for the excursion. For instructions on downloading data logger data, see page 9 of our Data Logger Instruction Manual.

7. If necessary, reset and reinstall your data logger so that the storage unit with vaccine continues to be monitored. Use your backup data logger if necessary.

8. Complete and submit this form. Attach data logger files, if applicable. We will contact you as soon as possible. If you are submitting this form after business hours, we will contact you on the next business day.

Questions? hhsiz@mt.gov 444-5580

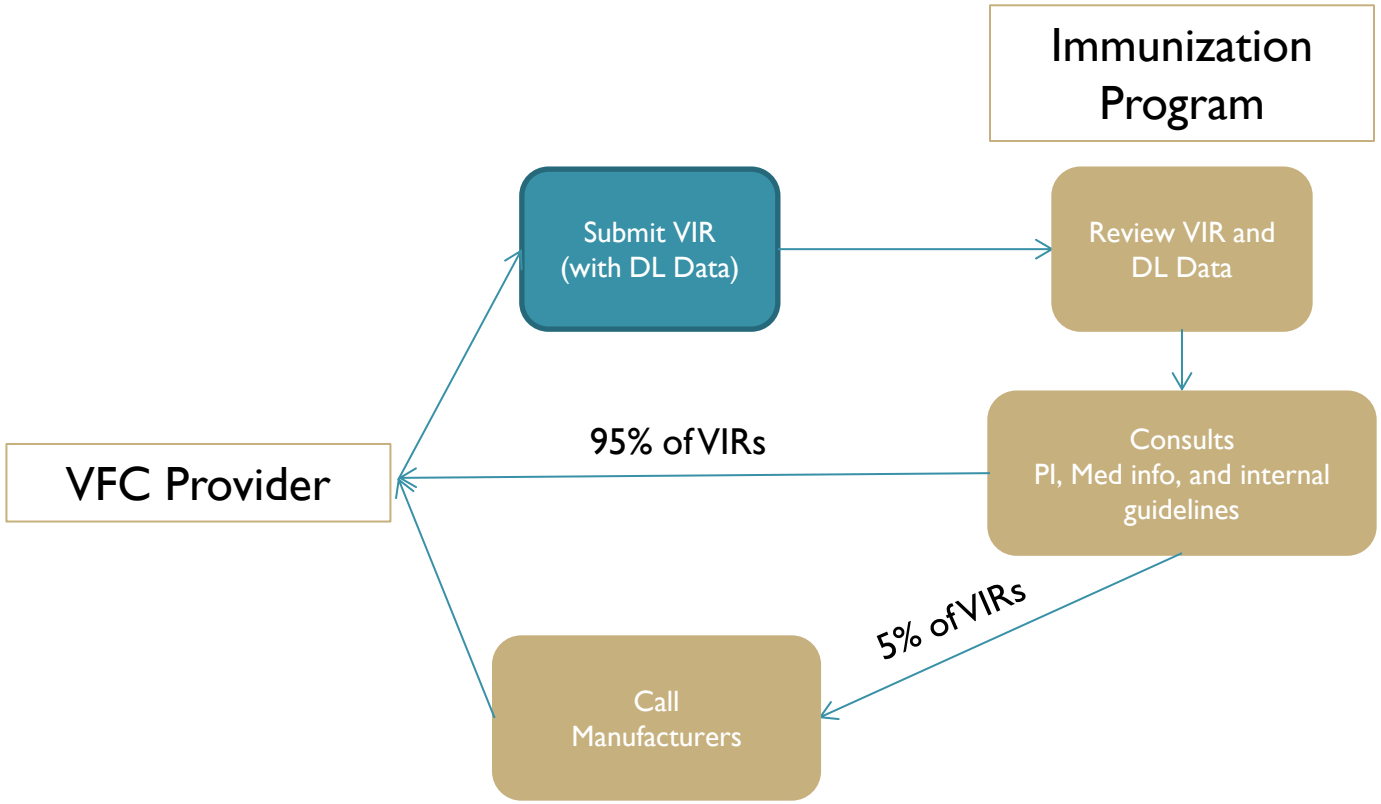
Facility Name and VFC PIN *

Your Name *

First Last

Vaccine Incident Reports

Process



Vaccine Incident Reports

Calling Manufacturers

- Scientific/Medical Information

- What do manufacturers need?
  - Product names
  - Max/Min Temperature
  - Duration Out of Range
  - Merck requires lot numbers and expiration dates.

- What do manufacturers provide?
  - Whether they have "In-house Stability Data" to support the continued use of the vaccine based on the temperature parameters provided. You decide whether to continue using the product.
  - Manufacturer cannot "Recommend the use of any product stored outside the parameters listed on the prescribing information." That would be an "off label" recommendation.
  - May require the information be given to a healthcare professional.
  - Case number
  - Can provider information in writing

Vaccine Incident Reports

Immunization Program Response

PROVIDER PIN	NDC	LOT NUMBER	QUANTITY	EXPIRATION DATE	TRADE NAME	MANUF	DISPOSITION	CASE#/SOURCE	REVACCINATE
000	00005-1971-02	M29048	10	3/31/2017	Prevnar 13	Pfizer	Ok to use to labeled expiration date	Med Info Letter	Not applicable
000	00006-4045-41	J012212	7	2/18/2016	Gardasil	Merck	Ok to use to labeled expiration date	Prescribing Information	Not applicable
000	00006-4045-41	J006236	9	2/25/2016	Gardasil	Merck	Ok to use to labeled expiration date	Prescribing Information	Not applicable
000	00006-4681-00	K004948	9	4/4/2016	MMR II	Merck	Waste	1-14183948700	Provide to Immunization Program the initials and date of vaccination of any patient administered this lot after 5:45PM on February 1, 2016
000	00006-4681-00	L007217	10	3/3/2017	MMR II	Merck	Waste	1-14183948700	Provide to Immunization Program the initials and date of vaccination of any patient administered this lot after 5:45PM on February 1, 2016
000	00006-4897-00	L030870	9	6/10/2018	PedvaxHIB	Merck	Ok to use to labeled expiration date	1-14183948700	Not applicable
000	00006-4995-00	J009374	10	6/11/2016	Recombivax-Adult	Merck	Ok to use to labeled expiration date	1-14183948700	Not applicable
000	49281-0860-10	K1330-1	7	6/20/2016	IPOL	Sanofi	Waste if opened. Ok to use to labeled expiration date if unopened.	4064283317	Not applicable
000		UI441AA	19	6/30/2016	Fluzone MDV (quad)	Sanofi	Waste if opened. Ok to use to labeled expiration date if unopened.	4064283317	Revaccinate any patient given this lot after 5:45PM on February 1, 2016
000	58160-0810-52	2CK29	10	10/16/2017	Infanrix	GSK	Ok to use to labeled expiration date	492166-1696712208	Not applicable
000	58160-0811-52	J5TZ7	9	8/27/2017	Pediarix	GSK	Ok to use to labeled expiration date	492166-1696712208	Not applicable
000	58160-0812-52	D592C	7	9/29/2017	KINRIX	GSK	Ok to use to labeled expiration date	492166-1696712208	Not applicable
000	58160-0825-52	49LH2	9	11/20/2017	Havrix-Peds 2 Dose	GSK	Ok to use to labeled expiration date	492166-1696712208	Not applicable
000	58160-0826-52	XD72G	6	11/5/2016	Havrix-Adult	GSK	Ok to use to labeled expiration date	492166-1696712208	Not applicable
000	58160-0842-52	37S2B	19	4/10/2016	Boostrix	GSK	Ok to use to labeled expiration date	492166-1696712208	Not applicable
000	58160-0842-52	D93LR	9	12/18/2016	Boostrix	GSK	Ok to use to labeled expiration date	492166-1696712208	Not applicable
000	58160-0842-52	9N74F	10	8/19/2017	Boostrix	GSK	Ok to use to labeled expiration date	492166-1696712208	Not applicable
000	58160-0842-52	2729X	10	9/15/2017	Boostrix	GSK	Ok to use to labeled expiration date	492166-1696712208	Not applicable

Excursion Parameters

	Duration	Max Temp
Refrigerator	14 hours 15 minut	64.8F

Vaccine Manufacturer Contact Information

GlaxoSmithKline	888-825-5249	MedImmune	877-633-4411
Merck	800-637-2590	Novartis	800-244-7668
Sanofi Pasteur	800-822-2463	Wyeth	800-438-1985

1) GSK-Call (866)475-8222 and select option 4.

Vaccine Incident Reports

Immunization Program Response

Email and possibly a phone call followed up by an email:

- Instructions to:
  - Dispose of vaccines according to attached table
  - Fill out Wasted and Expired Form with VIR# to start process to return wasted vaccines
  - Mark vaccines that you can continue to use so they can be identified as having gone through this excursion (cumulative)
  - Log event on trouble-shooting log (cold chain certification)

- Depending on Circumstance may include:
  - Revaccination instructions
  - Trouble-shooting guidance
  - Negligence determination
  - Reimbursement request
  - Repair or replacement instructions

Temperature Excursions, Wastage, and Negligence

2015 - The Year in Review

2015 Vaccine Incident Report Data	
Total VIRs submitted	981
Temperature excursions	652
Incidents of negligence	31
Incidents of wasted vaccine	32
Negligence that wasted vaccine	20
Reimbursements	4
Revaccinations	0

Data Logger Update

Time Flies When You're Having Fun

- Five years since the start of our Data Logger Program!
  - New VFC requirement nation-wide.
  - We are way ahead of the curve.
  - Our program is serving as a model for other states.
  - Super proud and appreciative of our providers!

- New recommendation for backup data loggers:
  Store in the refrigerator. Doors and crispers are fine.

- Calibrations are due this fall:
  - We will swap out your old data loggers with freshly calibrated devices
  - Install new
  - Return old
  - Monitor for 5 days and send approval data using VIR

Watch your email for detailed instructions

Vaccine Transport

General Policy

- CDC discourages the regular transport of public vaccine and encourages direct shipment from McKesson to the end user.

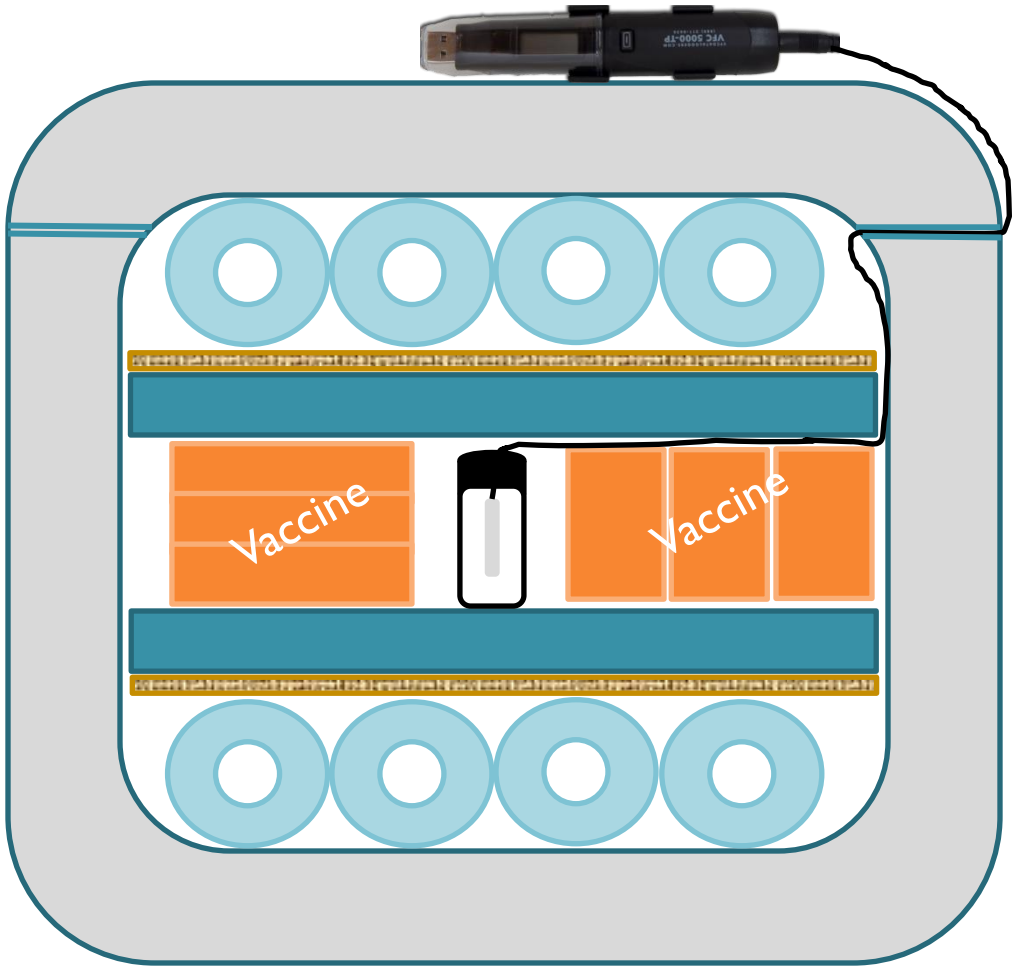
- Three reasons to transport vaccine:
  - Prevent wastage due to expiration
  - Off site clinics
  - Emergencies

- Use electric coolers if possible. More info from CDC to come as they test electric coolers.

- Use a validated pack-out for non-electric coolers.

Vaccine Transport

New Validated "Pack-Out" for Non-electric Coolers



Materials

- Hard-sided cooler with ≥2 inch walls
- Frozen, conditioned plastic water bottles (2 layers)
- Cardboard (2 layers)
- 1 inch thick insulating material (2 layers)
- Data Logger with buffered probe

DO NOT USE:

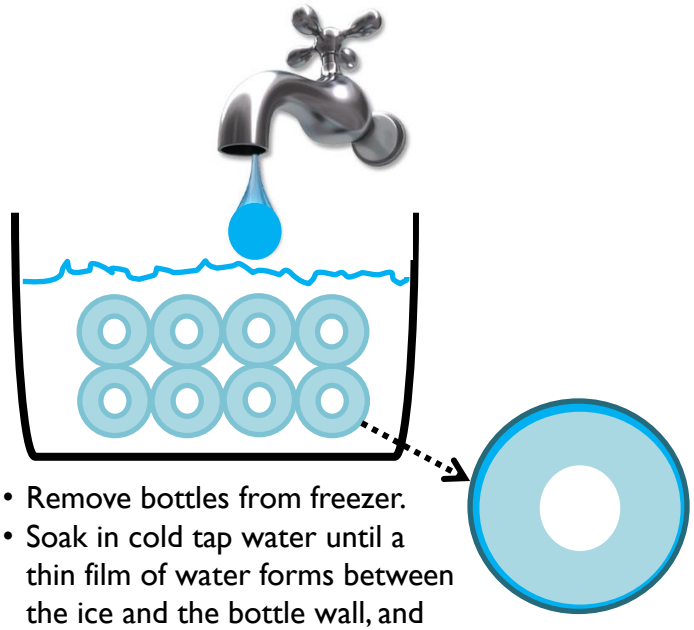
- Cool packs from McKesson shipments
- Dry ice
- Soft-sided coolers
- Cold Chain Monitors

Vaccine Transport

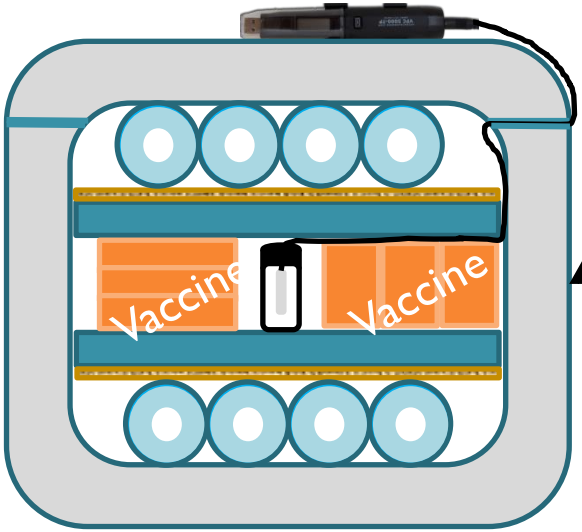
Frozen, Conditioned Water Bottles

- Store in freezer until use.
- Will help stabilize freezer temperatures.

To condition for pack-out:



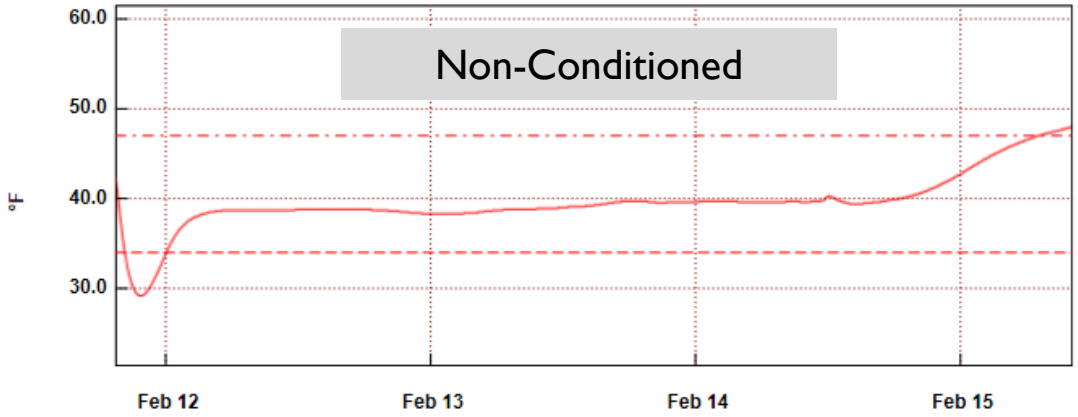
- Remove bottles from freezer.
- Soak in cold tap water until a thin film of water forms between the ice and the bottle wall, and the ice spins freely in the bottle. This takes about 3 minutes.



- Remove bottles from water and blot dry.
- Arrange conditioned bottles in cooler according to pack-out instructions.

Vaccine Transport - Pack-Out

Conditioned vs. Non-conditioned Water Bottles



Full Session Current View

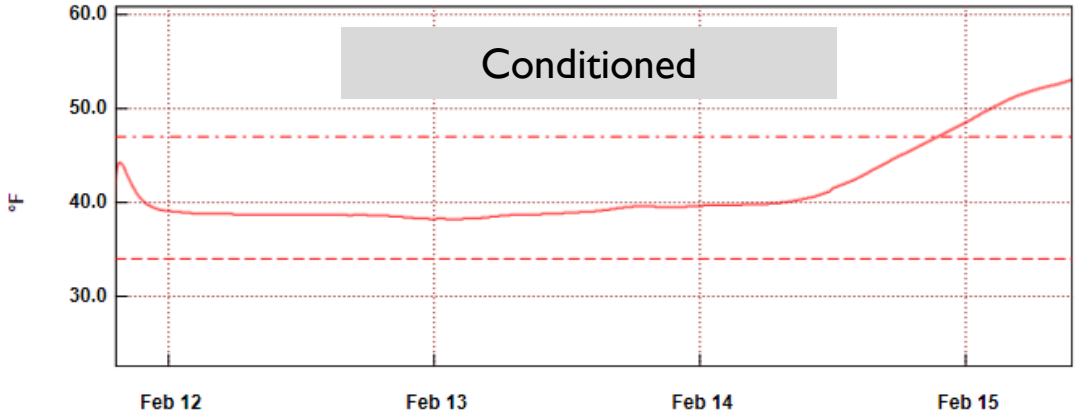
Fahrenheit(°F)

Max: 48.1 Min: 29.3

Avg: 39.7 Std: 3

In-range: 3 days 7 hours

≤ Freezing: 3 hours 40 minutes



Full Session Current View

Fahrenheit(°F)

Max: 53.2 Min: 38.3

Avg: 41.4 Std: 4.2

In-range: 3 days 2 hours

Vaccine Transport

Best Practices

Transport

Dos:

- Limit amount transported to only what is needed
- Develop a paper temperature log for transports
- Record time and temperature when moving vaccine to and from transport cooler
- If out-of-range temperatures occur, treat as any temperature excursion:
  - Return to monitored ref/freezer
  - DO NOT USE
  - Submit VIR with data logger data
  - Wait for our response on viability
- For electric 12V coolers – determine if your vehicle power outlet is switched (off when car is off) or unswitched (on all the time)

Don'ts:

- Carry transport coolers in the trunk of vehicles or leave coolers in vehicle for extended periods of time.

Off-Site Clinics

Dos:

- After transport, transfer vaccine to on-site ref/freezer with temperature monitoring (data logger with twice daily paper logging)

Avoid:

- Working out of the transport cooler unless it is electric and plugged in.
- If you must work out of transport cooler:
  - Use data logger and log hourly on paper
  - Have only 1 multi-dose (MDV) and 10 single-dose S/V removed for administration at a time.

Vaccine Transport

Special Circumstances

Multi-Dose Vials

- Only transport opened, multi-dose vials in an emergency and only within the same organization.
- NEVER transport opened, multi-dose vials between organizations/providers or across state lines.

Frozen Vaccine (Varivax® Proquad ®)

- Use an electric cooler/freezer

OR

- Transport with refrigerator vaccines
  - Put barrier between refrigerated and frozen vaccines so they aren't touching
  - Use frozen vaccine within 72 hours
  - If not used, return to freezer and submit a VIR:
    - DO NOT USE
    - Submit VIR with data logger data (for transport cooler) and times vaccine was removed and returned to regular storage
    - Wait for our response on viability

Questions?